

CLAIMS

1. A method for producing a drug containing composite  
particle, being characterized by comprising the step of giving  
5 a pressure and a shearing force to a mixture, constituted of  
two or more kinds of powder materials including a drug  
powder, so as to combine the powder materials with each  
other.

10 2. The method as set forth in claim 1, wherein the  
mixture includes a diluting agent powder.

3. The method as set forth in claim 2, wherein the  
diluting agent powder is selected from a group of celluloses  
15 and starches.

4. The method as set forth in claim 2 or 3, wherein an  
average particle diameter of the diluting agent powder is not  
less than one and not more than 10000 times as large as an  
20 average particle diameter of the drug powder.

5. The method as set forth in claim 2 or 3, wherein an  
average particle diameter of the diluting agent powder is 1  $\mu\text{m}$   
or more and 5000  $\mu\text{m}$  or less.

6. The method as set forth in claim 1 or 2, wherein an average particle diameter of the drug powder is 0.01  $\mu\text{m}$  or more and 500  $\mu\text{m}$  or less.

5        7. The method as set forth in claim 1 or 2, wherein a ratio at which the drug powder is contained in the drug containing composite particle is 0.01 wt % or more and 90 wt % or less.

10       8. The method as set forth in claim 1 or 2, wherein the drug powder is an antipyretic analgesic or an antiphlogistic.

9. A method for producing a drug containing composite particle containing a drug and a biocompatible polymer, being  
15 characterized by comprising the steps of: making at least one of the drug and the biocompatible polymer into a nano particle whose average particle diameter is less than 1000 nm; and making a mixture containing the nano particle into a composite particle in accordance with a fluid bed dry  
20 granulation method or a dry mechanical particle combining method, so as to form a polymer nano composite particle.

10. A method for producing a drug containing composite particle, being characterized by comprising: a primary particle  
25 formation step of forming primary particles each of which

includes nano particles whose average particle diameter is less than 1000 nm; and a combining step of combining the primary particles with each other so that the primary particles are reversibly collected, wherein a drug powder is used as the nano particles or the primary particles.

11. The method as set forth in claim 10, wherein each of the primary particles is a nano particle clump obtained by clumping a plurality of the nano particles.

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12. The method as set forth in claim 10 or 11, further comprising a nano particle formation step of forming the nano particles in accordance with spherical crystallization.

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13. The method as set forth in claim 10 or 11, wherein, in the combining step, the primary particles are subjected to secondary granulation in accordance with a fluid bed dry granulation method.

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14. The method as set forth in claim 13, wherein an average particle diameter of the primary particles is within a range of from 0.01  $\mu\text{m}$  or more to 500  $\mu\text{m}$  or less.

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15. The method as set forth in claim 13 or 14, wherein a binder is used to combine the primary particles with each

other in the fluid bed dry granulation method.

16. The method as set forth in claim 15, wherein the binder is an aqueous solution of a biocompatible polymer.

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17. The method as set forth in claim 10 or 11, wherein, in the combining step, the primary particles are made to adhere to a surface of each of carrier particles, which are larger than the primary particles in terms of an external diameter, in accordance with a dry mechanical particle combining method.

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18. The method as set forth in claim 17, wherein: an average particle diameter of the primary particles is within a range of from 0.01  $\mu\text{m}$  or more to 500  $\mu\text{m}$  or less, and an average particle diameter of the carrier particles is within a range of from 1  $\mu\text{m}$  or more to 500  $\mu\text{m}$  or less.

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19. The method as set forth in claim 17 or 18, wherein a polysaccharide powder or a hydrophilic polymer powder is used as the carrier particle.

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20. The method as set forth in claim 17 or 18, further comprising a carrier particle surface modification step of modifying the surface of the carrier particle, in accordance

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with a fluid bed dry granulation method or the dry mechanical particle combining method, before carrying out the combining step.

5           21. The method as set forth in claim 20, wherein, in the carrier particle surface modification step, the surface of the carrier particle is smoothed in accordance with the fluid bed dry granulation method or the dry mechanical particle combining method, or the carrier particle is combined with  
10 lubricant particles, so as to modify the surface of the carrier particle.

          22. The method as set forth in any one of claims 9, 10, and 11, being used to produce a powdery drug which is  
15 delivered to a lung and is absorbed through the lung.

          23. A method for producing a drug containing composite particle, being characterized by comprising the step of making a mixture, containing nano particles whose average particle  
20 diameter is less than 1000 nm and a drug powder whose average particle diameter is larger than the average particle diameter of the nano particles, into a composite particle in accordance with a fluid bed dry granulation method or a dry mechanical particle combining method, so as to modify a  
25 surface of the drug powder.

24. The method as set forth in claim 23, wherein a lubricant powder is used as the nano particles.

5           25. The method as set forth in claim 24, wherein a colloidal inorganic compound powder or a surfactant powder is used as the lubricant powder.

10           26. The method as set forth in claim 25, wherein the colloidal inorganic compound powder is colloidal silica.

27. The method as set forth in claim 25, wherein the surfactant powder is magnesium stearate or sugar ester.

15           28. The method as set forth in claim 23, wherein a polymer nano particle obtained in accordance with spherical crystallization is used as the lubricant powder.

20           29. The method as set forth in claim 28, wherein the polymer nano particle is constituted of a lactic acid · glycolic acid copolymer or hydroxymethyl cellulose phthalate.

25           30. The method as set forth in claim 23 or 24, wherein the average particle diameter of the drug powder is within a range of from 0.01  $\mu\text{m}$  or more and 500  $\mu\text{m}$  or less.

31. The method as set forth in claim 23 or 24, being used to produce a powdery drug which is delivered to a lung and is absorbed through the lung.